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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/590,552   | 08/23/2006  | Yoshitaka Ito        | 10873.1940USWO      | 6707             |
| 53148 7590 07/07/2009<br>HAMRE, SCHUMANN, MUELLER & LARSON P.C.<br>P.O. BOX 2902-0902<br>MINNEAPOLIS, MN 55402 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| BHAT, NARAYAN KAMESHWAR  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1634   |             |                      |                     |                  |
| MAIL DATE  |             | DELIVERY MODE        |                     |                  |
| 07/07/2009   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/590,552

**Applicant(s)**

ITO ET AL.

**Examiner**

NARAYAN K. BHAT

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56, 59-63, 66, 69, 72 and 73 is/are pending in the application.  
4a) Of the above claim(s) 61-63, 66, 69, 72 and 73 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 56, 59 and 60 is/are rejected.  
7) ☒ Claim(s) 56 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 23 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/23/2006  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This action is in response to papers filed on April 28, 2009.

#### ***Election/Restrictions***

2. Applicant's election with traverse of group I, claims 56, 59 and 60 in the reply filed on April 28, 2009 is acknowledged. The traversal is on the grounds that the instant claim 56 is the special technical feature common to all claims. This is not found persuasive because as described in the office action mailed April 1, 2009, the common technical feature is a microarray device comprising a substrate on which at least one probes is immobilized to detect bacteria associated with degradation of organochlorine compound. However, a microarray device for detecting bacteria associated with degradation of organochlorine compound is taught by Deneff et al. Therefore, the technical feature linking groups I to IV does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention.

Applicants further argue that Deneff et al teaches microorganisms that degrade PCBs (polychlorinated biphenyls) and the PCBs are chemical substances different from PCE (perchloroethylene) to which the present invention is directed. This argument is not persuasive because claim 56 requires anaerobic bacteria related to degradation of the organochlorine compound and not the PCE as Applicant asserts and therefore arguments are not persuasive. Furthermore, as described in the office action mailed on

April 1, 2009, Deneff et al teaches an oligonucleotide microarray device comprising probes for organochlorine compound degrading genes for simultaneous monitoring of microorganisms in the environment associated with degradation of organochlorine compound, i.e., PCB (Abstract, Fig. 6). It is also noted that the Deneff et al teaches *Rhodococcus* bacteria, which is the preferred bacteria associated with the degradation of organochlorine compound of the instant claim 56.

Furthermore, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps are able to stand alone (See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the preamble is directed to a species of "organochlorine compound" (i.e., PCE or TCE), while body of the claim is directed to a genus comprising "organochlorine compound". MPEP (2131.02) states that a genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named (Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Since the claimed method step is directed a genus comprising "organochlorine compound" which includes PCB compound taught by Deneff et al, Applicant's arguments are not persuasive.

The lack of unity requirement is still deemed proper and **therefore made FINAL.**

3. Claims 56, 59-63, 66, 69 and 72-73 are pending in this application.

4. Claims 61-63, 66, 69 and 72-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention of group II to IV there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 28, 2009.
5. Claims 56, 59 and 60 are under prosecution.
6. It is also noted that Applicants have elected the combination of SEQ ID NOS 19 to 105 as a single combination of nucleic acid probes with regard to claim 56 for further prosecution.

***Priority***

7. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application PCT/JP05/03175, on Feb. 25, 2005 and is accepted.

Applicants claim the benefit of a prior-filed application JP 2004-050082 and JP 2004-050083 is acknowledged. However, Applicants have not provided the English translation of the certified copy of the original document filed with the application. To obtain the priority date Applicant has to file the requested documents meeting the requirement as cited in 37 CFR 1.55. Since certified English translation of the prior filed application is not provided, the priority date for the instant application is Feb. 25, 2005.

***Information Request -37CFR 1.105***

8. It is noted that Applicants have presented a poster at the Society for Biotechnology, Japan in 2003, prior to filing the instant application (cited in the IDS filed August 23, 2006) related to the claimed invention (Scott et al, Construction of a 16S-23S ribosomal DNA internal transcribed spacer sequence based microarray for detection of PCE degrading microorganisms). In that meeting, Applicants have presented sequence information of internal transcribed spacer region of the 16 known PCE-degrading microorganisms and have designed an oligonucleotide microarray exclusively from the ITS sequences of said 16 bacteria to demonstrate that the designed probes based on the ITS are capable of distinguishing different bacteria at the species as well as at the strain level. Applicants have also presented the target gene amplification method using sense and antisense primers from bacteria derived from contaminated soil. The information presented at the meeting in 2003 comprises the claimed invention as recited in instant claims 56, 59 and 60 and is a bonafide prior art barring secondary considerations.

Therefore detailed information about the name, type and species of 16 known bacteria, the oligonucleotide probe sequence used for microarray and the primer sequence to amplify the said 16 bacteria presented at the meeting are requested for further review (See MPEP ss 704.12 and 37 C.F.R. 1.105).

***Claim Objections***

9. Claim 56 is objected to because of the following informalities: Claim 56 ends with multiple periods (see sub-sections 1 to 4). Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations (See MPEP 608 .01(m) for further guidance). Appropriate correction is required.

***Claim Rejections - 35 USC § 102/103***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 56, 59 and 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scott et al (The society for Biotechnology, Japan, 55<sup>th</sup> meeting 2003, 2J09-3, cited in IDS filed Aug. 23, 2006).

Regarding claims 56, 59 and 60, Scott et al teaches a method of judging a biological activity in an environment contaminated with an organochlorine compound tetrachloroethylene (PCE) as claimed.

The information presented at the meeting summarizes the claimed invention including amplifying a nucleic acid extracted from an environmental sample by a gene amplification method so as to use the amplified product as a target and hybridizing the target to a DNA probe including a base sequence unique to each of the 16 known PCE-degrading microorganisms (as listed in the instant claim), which are related to degradation of the organochlorine compound, in an attempt to detect the 16 types of bacteria in the environment (Abstract, pgs. 1 and 2).

Scott et al also teaches judging capability of the environment to eliminate the organochlorine compound based on degrading capability of the each of the 16 known bacteria that is detected with respect to the organochlorine compound and a de-chlorinated product thereof (Abstract and pgs. 1 and 2).

Scott et al further teaches designing oligonucleotide microarray derived against sequences from 16S-23S –ITS region of 16 PCE degrading bacteria and applying the



microarray for the detection of potential PCE degrading bacteria in the soil (Abstract and pgs. 1 and 2).

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Scott et al are silent with regard to SEQ ID NOS 19-105. However, Scott et al teaches that the DNA probes on the array are specific to any one of the 16 types of PCE degrading bacteria and are able to detect any potential PCE degrading bacteria in the soil (Abstract, Figs. 2 and 3), thus anticipates the claimed invention.

Alternatively, it would have been obvious to one of ordinary skill in the art to use the 16S-23S –ITS region sequence from 'A' to 'Q' bacteria and design the probe comprising SEQ ID NOS 19-105 for judging a biological activity in an environment contaminated with PCE as taught by Scott et al (Abstract).

The burden is on the Applicant to show that the claimed single combination of probes comprising SEQ ID NOS 19 to 105 and 'A' to 'Q' bacteria are non-obvious over the teachings of Scott et al.

14. Claims 56, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebersole et al (USPGPUB 2003/0077601 published April 24, 2003) in view of Buck et al (BioTechnique, 1999, 27, 528-536).

Ebersole et al teaches a method of judging a biological activity in an environment contaminated with an organochlorine compound that is at least one of tetrachloroethylene (PCE) and trichloroethylene (TCE), the method (paragraphs 0064

and 0106) comprising amplifying a nucleic acid extracted from an environmental sample by a gene amplification method so as to use the amplified product as a target (paragraphs 0012 and 0063).

Ebersole et al also teaches hybridizing the target to a DNA probe including a base sequence unique to each of 4 types of anaerobic bacteria denoted below as 'A', 'H', 'K' and 'M', which are related to degradation of the organochlorine PCE and TCE compound, in an attempt to detect the at least 4 different types of bacteria in the environment (paragraphs 0011, 0063, 0064 and 0106).

Ebersole et al also teaches judging capability of the environment to eliminate the organochlorine compound based on degrading capability of the each of 4 types of bacteria that is detected with respect to the organochlorine compound and a dechlorinated product thereof (Fig. 3, paragraphs 0030, 0064 and 0151). Ebersole et al do not teach 13 other bacteria listed in the instant claim.

Ebersole et al also teaches at least 66 different probes for the detection of PCE and TCE degrading bacteria and the like (Tables 1 to 4, paragraphs 0125 and 0126). Ebersole et al do not teach a combination of probes comprising SEQ ID NOS 19-105.

Regarding claim 59, Ebersole et al teaches a gene amplification using sense and antisense primer (Fig. 4, paragraphs 0031 and 0158). Ebersole et al do not teach primer sequence comprising SEQ ID NOS 116 and 117.

Regarding claim 60, Ebersole et al teaches that the contaminated environment is selected from a group consisting of soil or groundwater (paragraph 0104).

As described above, Ebersole et al teaches method steps as recited in the instant claims including bacteria that degrade PCE and TCE. Ebersole also teaches isolation, culturing of bacteria linked with degrading environmental contaminants, isolating DNA sequences of unique regions of dechlorinating bacteria (Figs. 1 and 2) paragraphs 0034-0042) and designing probes and primers from unique regions (paragraphs 0048, 0128 and 132). Ebersole et al do not teach claimed probes and primers with SEQ ID NOS 19 to 105, and 116 and 117. However, primers and probes for nucleic acid sequences were known in the art at the time of the claimed invention were made as taught by Buck et al.

Buck et al teaches primers/probes for nucleic acid amplification and further teaches that primers/probes for a nucleic acid sequence are generated using software or manually using different criteria (pg. 532, Software or Manual section of primers section). Buck et al also teaches 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby generating more than 1/3 of all possible primers on the 300 base pair sequence (see page 530, column 1). Buck et al further teaches that EVERY SINGLE PRIMER amplifies the target sequence (pg. 533, column 1) even though they are selected using different criteria (pg. 535, Discussion section) thus teaching every primer would have a reasonable expectation of success to detect PCE degrading bacteria.

Combined teaching of Ebersole et al and Buck et al would provide a primer and probe system comprising SEQ ID NOS 19-105 and 116-117 as claimed.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to design probes and primers that are equivalent to those claimed as SEQ ID NOS 19-105 and 116 and 117. The ordinary artisan would be motivated to design probes and primers that work in an equivalent fashion to those of SEQ ID NOS 19-105 and 116 and 117 because Buck et al teaches any primer will amplify the nucleic acid sequence of interest. The ordinary artisan would be motivated to use an alternative primer set with a reasonable expectation of success, because Buck teaches all primers work. The claimed SEQ ID NOS 19-105 and 116 and 117 are therefore obvious over Ebersole et al and Buck et al, absent secondary considerations.

### ***Conclusion***

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Douglas) Schultz can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Narayan K. Bhat

Examiner, Art Unit 1634

/JD Schultz/

Supervisory Patent Examiner, Art Unit 1635